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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1424]

Draft Guidance for Industry on Analytical Procedures and Methods Validation: Chemistry, Manufacturing, and Controls Documentation; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Analytical Procedures and Methods Validation: Chemistry, Manufacturing, and Controls Documentation.'' This draft guidance is intended to provide recommendations to applicants on submitting analytical procedures, validation data, and samples to support the identity, strength, quality, purity, and potency of drug substances and drug products. The recommendations apply to drug substances and drug products covered in new drug applications (NDA's), abbreviated new drug applications (ANDA's), biologics license applications (BLA's), product license applications (PLA's), and supplements to these applications.

DATES: Submit written comments on the draft guidance by [*insert date 90 days after date of publication in* **Federal Register**]. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance for industry to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or to the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1488, FAX 888–CBERFAX or 301–827–3844. Send one self-addressed adhesive label to assist the office in

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processing your requests. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. To expedite FDA review of your comments to the docket on this draft guidance, CDER requests that, if possible, you also send an electronic copy of these comments by e-mail to cunninghamp@cder.fda.gov.

FOR FURTHER INFORMATION CONTACT:

Radhika Rajagopalan, Center for Drug Evaluation and Research (HFD–645), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–5849, or

Alfred Del Grosso, Center for Biologics Evaluation and Research (HFM–250), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–435–4988.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Analytical Procedures and Methods Validation: Chemistry, Manufacturing, and Controls Documentation.'' This draft guidance is intended to assist applicants in assembling information, submitting samples, and presenting data to support analytical methodologies. The recommendations apply to drug substances and drug products covered in NDA's, ANDA's, BLA's, PLA's, and supplements to these applications. The principles also apply to drug substances and drug products covered in Type II drug master files.

The principles of methods validation described in this guidance apply to all types of analytical procedures; however, the specific recommendations in this guidance may not be applicable to certain analytical procedures unique to products such as biological, biotechnological, botanical, or radiopharmaceutical drugs.

This draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It represents the agency's current thinking on analytical procedures and methods validation. It does not create or confer any rights for or on any person and does not

operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written comments regarding the draft guidance by [*insert date 90 days after date of publication in the* **Federal Register**]. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Copies of this draft guidance for industry are available on the Internet at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/cber/guidelines.htm.

Dated: 8/18/00
August 18, 2000

Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 00–???? Filed ??–??–00; 8:45 am]

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